

Exhibit E

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Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue
Suite 729H
Washington, D.C. 20201
FOIARequest@psc.hhs.gov

Re: *Appeal of FOIA Request #23-00462-FOIA*

Dear FOIA Officer:

I represent the non-profit organization Freedom Coalition of Doctors for Choice (hereafter “Organization”). On January 3, 2023, I submitted on behalf of the Organization a request for records (hereafter “FOIA Request”) from the files of the Centers for Disease Control and Prevention (hereafter “CDC”) pursuant to the Freedom of Information Act (hereafter “FOIA”). On January 12, 2023, CDC responded to the FOIA Request (hereafter “Final Response”). The Organization writes now to appeal the Final Response.

Background:

On January 3, 2023, the Organization submitted a request to CDC for the following documents:

All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).

(Attachment 1.)

On January 12, 2023, CDC issued a Final Response letter which stated in relevant part:

Please be informed that the agency is withholding the v-safe free-text-fields data for the following reasons:

- *There are 7.8 million free-text field entries collected in v-safe from registered users that contain personal identifiable information (PII).*
- *The agency lacks the resources to manually review the data collected from these registrants.*

Alternatively, we are providing you with a copy of the “v-safe motivation survey” dataset. This dataset includes survey responses collected from v-safe participants from May 1, 2022, through June 31, 2022. After a careful review, some of the information has been withheld from release pursuant to FOIA Exemption 6.

(Attachment 2.)

Argument:

CDC’s withholding of the requested free text fields (hereafter “requested records”) violates FOIA in two ways. First, CDC has failed to provide any exemption to justify withholding the requested records and a proper final ‘determination.’ Secondly, even if it has determined that portions of the requested records are not reasonably segregable, and they contain information relevant to protected privacy interests under Exemption 6, CDC has failed to demonstrate whether such privacy interests outweigh the public’s interest in disclosure.

1. CDC failed to provide a FOIA Exemption or sufficient reasoning for withholding records.

CDC unlawfully withheld records without invoking a FOIA Exemption and did not provide the Organization with an adequate ‘determination’ as required under FOIA. When the sufficiency of “the release of information under the FOIA” is challenged, “the agency has the burden of showing that requested information comes within a FOIA exemption.” *Pub. Citizen Health Research Grp. v. FDA*, 185 F.3d 898, 904, (D.C. Cir. 1999). An agency withholding responsive documents from a [FOIA] release bears the burden of proving the applicability of the claimed exemptions.” *American Civil Liberties Union v. DOD*, 628 F.3d 612, 619 (D.C. Cir. 2011).

“[I]n order to make a ‘determination’ and thereby trigger the administrative exhaustion requirement, the agency must at least: (i) gather and review the documents; (ii) determine and communicate the scope of the documents it intends to produce and withhold, and *the reasons for withholding any documents*; and (iii) inform the requester that it can appeal whatever portion of the ‘determination’ is adverse.” *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188-89 (D.C. Cir. 2013) (Emphasis added); *see also* 5 U.S.C. § 552(a)(6)(A)(i) (“notify the person making such request of such determination *and reasons therefor*.”). “The statutory requirement that the agency provide ‘the reasons’ for its ‘determination’ strongly suggests that the reasons are particularized to the ‘determination’ — most obviously, the specific exemptions that may apply to certain withheld records.” *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d at 186; *see also Khine v. United States Dep’t of Homeland Sec.*, 943 F.3d 959, 967-968 (D.C. Cir. 2019) (Court held the agency “satisfied its obligation to ‘determine and communicate . . . the reasons for withholding any documents’ because they “provided reasons by listing and defining the exemptions that the agency applied to the records” withheld.) Such reasonings need to incorporate a FOIA exemption in order to satisfy the agency’s obligations under FOIA. *Khine*, 943 F.3d at 967-968.

In this instance, CDC’s Final Response did not provide the information necessary to justify its reasoning for withholding records. CDC’s Final Response declares “the agency is withholding the v-safe free-text-fields data” but never details the applicable FOIA Exemption that justify its withholding. (See Attachment 2). CDC claims all “7.8 million free-text field entries collected from registered users . . . contain personal identifiable information (PII).” *Id.* CDC further claims

that it “lacks the resources to manually review the data collected from these registrants.” First, if CDC does not have the resources to manually review the free text fields, how does it know all 7.8 million free text entries contain PII. It does not adequately prove this assertion. Second, CDC has not provided any information on whether most – if not all – the PII can be removed through more automated mechanisms, as opposed to only “manual[] review.” For example, Social Security numbers, birthdates, phone numbers, registrant numbers, city names, etc. can likely be redacted through automated mechanism, or at least this information could be flagged for relatively easy manual redactions. Furthermore, if the free text fields are represented in a standardized template, and the PII is routinely detailed in certain boxes or locations in the template, the agency can automate a redaction overlay, that redacts these PII locations on every record. Therefore, CDC has not provided sufficient reasoning to withhold the requested records. For all the reasons described above, CDC has failed to justify withholding the requested records and provide the Organization with a sufficient final ‘determination.’ *Citizens for Responsibility & Ethics in Wash.*, 711 F.3d 188-89.

2. CDC failed to demonstrate that any unreasonably segregable portions of the requested records contain protected privacy interests that outweigh the public’s interest under Exemption 6.

Even if CDC could demonstrate that the unreasonably segregable portions of the requested records contain protected privacy interests, CDC has failed to demonstrate those interests outweigh the public’s interests in the requested records. “An agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions.” *American Civil Liberties Union*, 628 F.3d at 619. Exemption 6 applies to prevent disclosure of “personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a “presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act.” *Multi AG Media LLC v. U.S. Dep’t of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat’l Ass’n of Homebuilders v. Norton*, 309 F.3d 26, 32 (D.C. Cir. 2002)) (internal quotation marks omitted). Therefore, an agency may withhold personal information only if “disclosure would compromise a substantial, as opposed to a de minimis, privacy interest.” *Nat’l Ass’n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989).

Furthermore, even when a privacy interests exist, courts must “weigh the privacy interest in non-disclosure against the public interest in the release of the records in order to determine whether, on balance, the disclosure would work a clearly unwarranted invasion of privacy.” *Lepelletier v. FDIC*, 164 F.3d 37, 46 (D.C. Cir. 1999) (internal quotation marks omitted); *see also U.S. Dep’t of State v. Washington Post Co.*, 456 U.S. 595, 598 (1982).

In this instance, CDC’s Final Response makes no indication whether the release of the information it has proven cannot be reasonably segregated would cause a “clearly unwarranted invasion of privacy.” *Lepelletier*, 164 F.3d 46. FOIA does not flatly prohibit the release of personal information that could cause an invasion of privacy. It only protects the release of personal information that would cause a clearly unwarranted invasion of privacy. Thus, the determination on whether an invasion of privacy is clearly warranted or not depends on the

public's interest and benefit in obtaining the released material. *Id.* In this case, the requested information the Organization seeks has insurmountable importance to the public, and yet CDC's Final Response provides no indication whether the public's interest in the requested records was even considered.

In consideration of this appeal, as CDC goes back to balance the privacy interests in non-disclosure versus the public's interest in disclosure, Organization provides the following information to emphasize the insurmountable public interest in the requested records:

CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."¹ One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."² A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Organization seeks in this request.

The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines – or as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.³ Without this information, which CDC currently possesses but is refusing to disclose, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

Failure to disclose this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. This would compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.⁴ That is, for example, the core mission of React-19, a non-profit comprised of many individuals, and medical professionals, seriously injured from COVID-19 vaccines.

The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic

¹ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>.

² <https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf>.

³ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html>.

⁴ Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harms – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated. The information derived from the free text fields can help provide information to alleviate some of these issues.

The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign in order to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.⁵ This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.⁶ With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS' "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.⁷ The refusal to disclose the requested records would deny families the information they need to provide their informed consent to the external pressures and

⁵ <https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules>.

⁶ <https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/>.

⁷ *Id.*

messaging resulting from the current administration's actions.

Lastly, if the requested information is disclosed, the Organization will, and has the capacity to make the information immediately available to the public. The Organization is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt.

Appellate Request:

For all the reasons detailed above, the Freedom Coalition of Doctors for Choice appeals CDC's Final Response and requests the agency make a determination with respect to this appeal in 20 days as FOIA requires. Thank you for your time and consideration into this matter. If you have any questions regarding this appeal, please feel free to contact me at Chris@cwiestlaw.com or 513-257-1895.

Regards,

/s Christopher Wiest
Christopher Wiest